## UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF FLORIDA

| CASE NO. |  |
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## UNITED STATES OF AMERICA

Plaintiff,

VS.

DR. CHAD LIVDAHL, N.D., DR. ZARAH KARIM, N.D., TOXIN RESEARCH INTERNATIONAL, INC., POWDERZ, INC., THE COSMETIC PHARMACY, INC., and Z SPA, INC.,

| Defendants. |  |   |
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## MOTION FOR EMERGENCY TEMPORARY RESTRAINING ORDER, PRELIMINARY AND PERMANENT INJUNCTION

The United States of America, plaintiff, by and through the undersigned Assistant United States Attorney, hereby respectfully moves this Court, pursuant to Rule 65 of the Federal Rules of Civil Procedure, pursuant to the Court's authority under 21 U.S.C. § 332 and 18 U.S.C. § 1345, to restrain and enjoin defendants Toxin Research International, Inc., Powderz, Inc., The Cosmetic Pharmacy, Inc., Z-Spa, Inc., Dr. Chad Livdahl, N.D., Dr. Zarah Karim, N.D., individuals, and each and all of their officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), from directly or indirectly causing the shipment of Botulinum Toxin Type A in interstate commerce, using Botulinum Toxin Type A on human beings, presenting educational seminars and courses, and distributing

informational and/or promotional materials, referring or related in any manner whatsoever to Botulinum Toxin Type A.

The defendants are in violation of the Food and Drug Cosmetics Act, 21 U.S.C, § 301, et. seq. Defendants' labels attached to its product, Botulinum Toxin Type A, its advertisements, promotion materials, and brochures all state that the Botulinum Toxin Type A is to be used for research purposes only, and is not for use on humans. However, defendants have manifested a clear intent to distribute in interstate commerce, Botulinum Toxin Type A, to non-research entities, for use in humans, as a drug that is intended to affect the structure and/or function of the human body, as defined in 21 U.S.C. § 321(g)(1), and manifest a clear intent to promote the Botulinum Toxin Type A for such human use. The defendants thus cause drugs that are misbranded, as defined in 21 U.S.C. § 352(f), to be shipped in interstate commerce, in violation of 21 U.S.C. § 331(a).

Furthermore, defendants represented to federal Food and Drug Administration investigators that they did not sell their product to physicians or entities engaged in human, non-research use. However, defendants' actions and sales subsequent to their statement to the FDA inspectors demonstrate the contrary. Defendants have thus violated 18 U.S.C. §§ 371 and 1001, and thus must be enjoined under 18 U.S.C. § 1345. Defendants' actions and practices place the public at great risk and should be halted by this Court preliminarily and permanently.

This motion is supported by the accompanying Complaint, legal memorandum, and the Declarations of FDA Special Agent Susan J. Leeds, Office of Criminal Investigation, along with the twenty-five accompanying exhibits, and FDA Special Agent Tina Stasulli Korb, and one accompanying exhibit.

Respectfully submitted,

MARCOS DANIEL JIMENEZ UNITED STATES ATTORNEY

By:

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